

REMARKS

Claims 1-163 are presently pending in this application. Claims 44-67, 71-150, and 155-163 are withdrawn from consideration. Claim 23 is cancelled with this amendment. The Applicants respectfully request that Claims 1, 34-37, 68, and 152-154 be amended as shown above. This amendment is supported by the specification at paragraph 0031. No new matter has been added by this amendment.

Specification

The disclosure has been objected to for failing to include an abstract as required by 37 CFR 1.72(b). This objection is overcome by the amendment of the specification herein. No new matter has been added by this amendment.

Claim Rejections:

35 U.S.C. §103

Reconsideration is requested of the rejection of claims 1-43, 68-70, and 151-154 under 35 U.S.C. §103(a) as being unpatentable over Oletta (GB 890,614, hereinafter Oletta '614). The claims have been amended to more clearly define Applicant's invention, which comprises the use of reverse phase preparative chromatography as a method of purifying crude alkaloid feed on a commercial scale.

Oletta '614 discloses the use of traditional preparative chromatography, although there is not enough data given to determine the actual loading ratio. Traditionally, as in Oletta '614, preparative chromatography is used to purify a new compound in the laboratory, using normal phase chromatography. The silica is used to adsorb any color or tarry material from the product. The silica cannot be regenerated, and often needs to be replaced after one use. This method is not practical for use in manufacturing a compound.

The Applicant's method uses **reverse phase chromatography**, not the normal phase disclosed in Oletta '614. The independent claims have been amended to more clearly limit the

Amendment A

Inventor(s) Name: Antonini, Enrico, A.

Attorney Docket No.: 1580 WO/US

claimed invention to reverse phase. There is no disclosure, teaching or suggestion to use reverse phase chromatography in Oletta '614.

Additionally, Oletta '614 teaches the use of traditional preparative chromatography to recover a single compound. Nowhere does Oletta '614 disclose, teach, or suggest the use of preparative chromatography for the separation of multiple alkaloids from a crude alkaloid feed in industrial production. Moreover, the claims have been amended to more clearly define Applicant's invention as being preparative chromatography, with loading ratios of no more than 1000.

Further, Oletta '614 does not teach the appropriate mobile phase, optimal particle size of the stationary phase, or collection times as disclosed and claimed by the Applicant's. For example, Oletta '614 discloses the use of benzene, which is inappropriate for reverse phase chromatography. (It is noted that the particle sizes and collection times are not limitations in the broadest claims.)

In the absence of any disclosure of the combination as claimed by the Applicant's, a *prima facie* case for obvious is lacking. Withdrawal of the rejection of claims 1-43, 68-70, and 151-154 under 35 U.S.C. §103(a) as being unpatentable over Oletta (GB 890,614) is therefore respectfully requested.

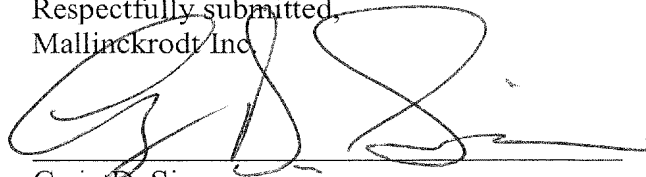
Finally, in #7 of the Office Action, the Examiner writes that the claims are objected to for containing non-elected subject matter. From the record before me, it is my understanding that the Examiner made a restriction requirement, and Applicant's elected Group I corresponding to these claims, which the Examiner wrote were a method of separating morphine. It is my assumption this objection would be overcome by the allowance of the broadest claim, claim 1 as amended.

If any issue regarding the allowability of any of the pending claims in the present application could be readily resolved, or if other action could be taken to further advance this application, or if the Examiner should have any questions regarding the present amendment, it is respectfully requested that the Examiner please telephone Applicant's undersigned attorney in this regard.

Amendment A
Inventor(s) Name: Antonini, Enrico, A.
Attorney Docket No.: 1580 WO/US

Date: 6-12-2007

Respectfully submitted,
Mallinckrodt Inc.

A handwritten signature in black ink, appearing to read 'Craig D. Siman', written over a horizontal line.

Craig D. Siman
Reg. No. 60,137
Telephone Number 314.654.3960
Facsimile 314.654.3156

Mallinckrodt Inc.
675 McDonnell Boulevard
St. Louis, Missouri 63042